FILED
05-273 AUG 29 2005
OFFICE OF THE CLERK

No. ___

IN THE

Supreme Court of the United States

FEDERAL TRADE COMMISSION,
Petitioner,

v.

SCHERING-PLOUGH CORPORATION, *et al.*

On Petition for a Writ of Certiorari to the United States Court of Appeals for the Eleventh Circuit

PETITION FOR A WRIT OF CERTIORARI

WILLIAM BLUMENTHAL
General Counsel
JOHN D. GRAUBERT *
Principal Deputy General Counsel
JOHN F. DALY
Deputy General Counsel for Litigation
IMAD D. ABYAD
Attorney
FEDERAL TRADE COMMISSION
600 Pennsylvania Ave., N.W.
Washington, DC 20580
(202) 326-2375

SUSAN A. CREIGHTON
Director
BRADLEY S. ALBERT
ELIZABETH R. HILDER
MICHAEL B. KADES
THOMAS G. KRATTENMAKER
Attorneys
BUREAU OF COMPETITION

* Counsel of Record

WILSON-EPES PRINTING CO., INC. – (202) 789-0096 – WASHINGTON, D. C. 20001

QUESTIONS PRESENTED

1. Whether an agreement between a pharmaceutical patent holder and a would-be generic competitor, in which the patent holder makes a substantial payment to the challenger for the purpose of delaying the challenger's entry into the market, is an unreasonable restraint of trade.

2. Whether the court of appeals grossly misapplied the pertinent "substantial evidence" standard of review, by summarily rejecting the extensive factual findings of an expert federal agency regarding matters within its purview.

PARTIES TO THE PROCEEDING

Petitioner is the Federal Trade Commission. Respondents, who were petitioners in the court of appeals below, are Schering-Plough Corporation, and Upsher-Smith Laboratories, Inc.

TABLE OF CONTENTS

	Page
Opinions below	2
Jurisdiction	2
Statutory provisions involved	2
Statement	2
Reasons for granting the petition	12
I. The court of appeals erred in ruling that agreements between competitors are lawful if within the "potential" reach of a patent claim	13
II. Review is needed to ensure uniformity on an issue of exceptional national importance	23
III. The court of appeals grossly misapplied the substantial evidence standard	26
Conclusion	29

TABLE OF AUTHORITIES

Cases:

In re Abbott Labs., FTC Dkt. No. C-3945 (May 22, 2000)	24
Andrx Pharms., Inc. v. *Biovail Corp. Int'l*, 256 F.3d 799 (D.C. Cir. 2001)	16
Astra Aktiebolag v. *Andrx Pharms., Inc.*, 222 F. Supp.2d 423 (S.D.N.Y. 2002), *aff'd sub nom. In re Omeprazole Patent Litig.*, 84 Fed. App. 76 (Fed. Cir. Dec. 11, 2003)	25
In re Bristol-Myers Squibb Co., FTC Dkt. No. C-4076 (April 14, 2003)	24
California Dental Association v. *FTC*, 526 U.S. 756 (1999)	17

Cases—Continued: Page

In re Cardizem CD Antitrust Litig., 332 F.3d 896 (6th Cir. 2003), *cert. denied sub nom. Andrx Pharms., Inc.* v. *Kroger Co.*, No. 03-779 (Oct. 12, 2004) 23
Dickinson v. *Zurko*, 527 U.S. 150 (1999) 28
Eli Lilly & Co. v. *Barr Labs., Inc.*, 251 F.3d 955 (Fed. Cir. 2001) 25
Eli Lilly & Co. v. *Medtronic, Inc.*, 496 U.S. 661 (1990) 20
Ethyl Gasoline Corp. v. *United States*, 309 U.S. 436 (1940) 13
FTC v. *Algoma Lumber Co.*, 291 U.S. 67 (1934) 27
FTC v. *Indiana Federation of Dentists*, 476 U.S. 447 (1986) 1, 9, 17, 26, 27, 28
FTC v. *Superior Ct. Trial Lawyers Ass'n*, 493 U.S. 411 (1990) 1
In re Geneva Pharms., Inc., FTC Dkt. No. C-3946 (May 22, 2000) 24
In re Hoechst Marion Roussel, Inc., FTC Dkt. No. C-3946 (May 8, 2001) 24
Kegel Co., Inc. v. *AMF Bowling, Inc.*, 127 F.3d 1420 (Fed. Cir. 1997) 14
Merck KGaA v. *Integra Lifesciences I, Ltd.*, No. 03-1237, 125 S. Ct. 2372 (June 13, 2005) 4
Palmer v. *BRG of Georgia, Inc.*, 498 U.S. 46 (1990) (per curiam) 15
874 F.2d 1417 (11th Cir. 1989) 15
SmithKline Beecham Corp. v. *Apotex Corp.*, 247 F. Supp.2d 1011 (N.D. Ill. 2003), *aff'd*, 403 F.3d 1331 (Fed. Cir. 2005) 25

Cases—Continued: Page

United States v. *Griffith*,
334 U.S. 100 (1948) 15
United States v. *Line Material Co.*,
333 U.S. 287 (1948) 13
United States v. *Masonite Corp.*,
316 U.S. 265 (1942) 13, 17
United States v. *Microsoft Corp.*,
253 F.3d 34 (D.C. Cir. 2001) 15
United States v. *Singer Mfg. Co.*,
374 U.S. 174 (1963) 13
Universal Camera Corp. v. *NLRB*,
340 U.S. 474 (1951) 26, 28
Valley Drug Co. v. *Geneva Pharms., Inc.*,
344 F.3d 1294 (11th Cir. 2003), *cert. denied*
sub nom. Walgreen Co. v. *Abbott Labs.*,
No. 03-1178 (Oct. 12, 2004) 11, 15
Wolverine World Wide, Inc. v. *Nike, Inc.*,
38 F.3d 1192 (Fed. Cir. 1994) 14
Zenith Radio Corp. v. *Hazeltine Research, Inc.*,
395 U.S. 100 (1969) 16

Statutes and regulations:

Drug Price Competition and Patent Term
Restoration Act of 1984, Pub. L. No.
98-417, 98 Stat. 1585 2
Magnuson-Moss Warranty–Federal Trade
Commission Improvement Act, Pub. L.
No. 93-637, 88 Stat. 2183,
§ 204(a) 1

Statutes and regulations—Continued: Page

Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, 117 Stat. 2066 2
§§ 1111-1118 5
§ 1112 21
5 U.S.C. 706(2)(E) 26
15 U.S.C. 1 2
15 U.S.C. 45 2
15 U.S.C. 45(b) 27
15 U.S.C. 45(c) 24, 26
15 U.S.C. 56(a)(3)(A) 1
21 U.S.C. 355(b)(1) 4
21 U.S.C. 355(j) 4
21 U.S.C. 355(j)(2)(A)(vii)(IV) 4
21 U.S.C. 355(j)(5)(B)(iii) 4, 20
21 U.S.C. 355(j)(5)(B)(iv) 4, 20
21 U.S.C. 355(j)(5)(D)(i)(V) 5, 21
28 U.S.C. 1254(1) 2
35 U.S.C. 271(e)(1) 4
35 U.S.C. 271(e)(2) 20
35 U.S.C. 282 14

Miscellaneous:

John R. Allison & Mark A. Lemley, *Empirical Evidence on the Validity of Litigated Patents*, 26 AIPLA Q.J. 185 (1998) 17
Centers for Medicare & Medicaid Services, *Highlights - National Health Expenditures, 2003* (January 11, 2005) 24

Miscellaneous—Continued: Page

Congressional Budget Office, *How Increased Competition from Generic Drugs Has Affected Prices and Returns in the Pharmaceutical Industry* (July 1998) 6, 21, 25
Drug Topics, *Top 200 Brand-Name Drugs by Retail Dollars in 2004* (Feb. 21, 2005) 25
Federal Trade Commission, *Generic Drug Entry Prior to Patent Expiration: An FTC Study* (July 2002) 5, 17, 21, 24
Federal Trade Commission, *Agreements Filed with the Federal Trade Commission under the Medicare Prescription Drug, Improvement, and Modernization Act of 2003: Summary of Agreements Filed in FY 2004–A Report by the Bureau of Competition* (Jan. 7, 2005) 22
Food and Drug Administration, *Savings from Generic Drugs Purchased at Retail Pharmacies* (May 3, 2004) 25
Generic Pharmaceuticals Marketplace Access and Consumer Issues: Hearing Before the Senate Commerce Comm., 107th Cong. (April 23, 2002) (statement of Kathleen D. Jaeger, President & CEO, Generic Pharmaceutical Ass'n) 6
H.R. Rep. No. 857, 98th Cong., 2nd Sess., Pt. 1 (1984) 3
The Henry J. Kaiser Family Foundation, *Prescription Drug Trends* (Oct. 2004) 24
Herbert Hovenkamp, *Antitrust Law* (1999 & 2004 Supp.)
¶ 2030b 15
¶ 2046 18

Miscellaneous—Continued: Page

Herbert Hovenkamp, Mark Janis & Mark A. Lemley, *Anticompetitive Settlement of Intellectual Property Disputes*, 87 Minn. L. Rev. 1719 (2003) 16
Mark A. Lemley & Carl Shapiro, *Probabilistic Patents*, 19 J. Econ. Perspectives 75 (2005) 16
Pfizer Inc., *Form 10-Q* (Aug. 8, 2005) 25
Purdue Pharma, L.P., *Press Release* (June 8, 2005) 25
S. Rep. No. 167, 107th Cong., 2nd Sess. (2002) ... 5, 20
Carl Shapiro, *Antitrust limits to patent settlements*, 34 RAND J. Econ. 391 (2003) 16
Sheryl Gay Stolberg et al., *Keeping Down the Competition; How Companies Stall Generics and Keep Themselves Healthy*, The New York Times, July 23, 2000 5
Wyeth, *Form 10-Q* (Aug. 5, 2005) 25

IN THE

Supreme Court of the United States

FEDERAL TRADE COMMISSION,
Petitioner,

v.

SCHERING-PLOUGH CORPORATION, *et al.*

ON PETITION FOR A WRIT OF CERTIORARI TO THE
UNITED STATES COURT OF APPEALS
FOR THE ELEVENTH CIRCUIT

PETITION FOR A WRIT OF CERTIORARI

The Federal Trade Commission, pursuant to the authority of 15 U.S.C. 56(a)(3)(A), respectfully petitions for a writ of certiorari to review the judgment of the United States Court of Appeals for the Eleventh Circuit in this case.[1]

---

[1] The Commission has exercised its authority to represent itself before this Court only twice previously, in the 30 years that it has had that authority. See Pub. L. No. 93-637, § 204(a), 88 Stat. 2183, 2199-2200 (1975); *FTC* v. *Indiana Federation of Dentists*, 476 U.S. 447 (1986) ("*IFD*"); *FTC* v. *Superior Ct. Trial Lawyers Ass'n*, 493 U.S. 411 (1990). The Commission takes this step now not only to seek correction of a ruling that conflicts with fundamental antitrust and administrative law principles, but because of the great urgency of the matter, in light of the billions of dollars of consumer savings on prescription drugs that the ruling below jeopardizes. See *infra* at 24-26.

OPINIONS BELOW

The opinion of the court of appeals (Pet. App. 1a-35a) is reported at 402 F.3d 1056. The order of the court of appeals denying rehearing and rehearing *en banc* (Pet. App. 341a-342a) is unreported. The Opinion of the Commission and Final Order (Pet App. 36a-153a) will be reported at 136 F.T.C. ___. The Initial Decision of the Administrative Law Judge (Pet. App. 154a-340a) will be reported at 136 F.T.C. ___.

JURISDICTION

The judgment of the court of appeals was entered on March 8, 2005. A petition for rehearing was denied on May 31, 2005. The jurisdiction of this Court rests on 28 U.S.C. 1254(1).

STATUTORY PROVISIONS INVOLVED

Relevant portions of the Sherman Act, 15 U.S.C. 1; the Federal Trade Commission Act, 15 U.S.C. 45; the Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (1984) ("Hatch-Waxman Act"); and the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, §§ 1101-1104, 1111-1118, 117 Stat. 2066, 2448-2464 (2003) ("2003 Medicare Amendments") are set out in an appendix to this petition. Pet. App. 343a-363a.

STATEMENT

In the Hatch-Waxman Act, Congress sought to speed the entry of low-cost generic drugs into the market by encouraging challenges to patent claims that stand impermissibly in the way of entry. The Act has been remarkably successful; generic challengers have prevailed in most cases in which courts have

ruled on arguments that drug patents were either invalid or not infringed by the challengers, and American consumers have saved billions of dollars as a result.

The present case involves a stratagem that a number of pharmaceutical companies have used to frustrate Congress's resolve to subject drug patents to scrutiny, by entering into agreements that allow them to delay the entry of generic drugs and share the profits derived from maintaining high drug prices. In the two agreements at issue here, the generic manufacturers agreed to delay sale of their products until specified future dates in exchange for cash payments from the patentee. Because the parties anticipated that the patentee's enhanced profits from delayed generic competition would far exceed the generic competitors' lost profits, the parties could share a windfall, at the expense of consumers. Petitioner Federal Trade Commission ("Commission") applied well settled antitrust principles to rule that those agreements unreasonably restrained trade by foreclosing the possibility of earlier generic entry, but the court of appeals set aside the Commission's decision on the ground that any competition forgone was within the "exclusionary potential" of the patent claims, regardless of the purpose or effect of the agreements. Pet. App. 17a. By protecting agreements in which patentees buy off potential challengers from effective antitrust challenge, the ruling below conflicts with fundamental antitrust principles and threatens to vitiate an important statute designed to promote the health and economic well-being of American consumers. The ruling comes at a crucial point. Of the twenty top-selling prescription drugs in the United States today, eleven, with annual sales of nearly $25 billion, are currently subject to litigation by generics seeking to enter the market. See note 23, *infra*.

1. Congress intended that the Hatch-Waxman Act would "make available more low cost generic drugs," while fully protecting legitimate patent claims. H.R. Rep. No. 857, 98th Cong., 2nd Sess., Pt. 1, at 14 (1984). The Act allows for